



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 19, 2022

OFFICE OF MISSION SUPPORT

Jones Walker LLP on Behalf of
Denka Performance Elastomer LLC
ATTN: Robert E. Holden, Boyd A. Bryan, Trey K. Bartholomew
201 St Charles Ave, Suite 5100
New Orleans, LA 70170

Dear Mr. Holden, Mr. Bryan, and Mr. Bartholomew,

This letter is in response to your Request for Reconsideration (RFR), received by the U.S. Environmental Protection Agency on June 10, 2022, which was assigned [RFR number 21005A](#) for tracking purposes. Your RFR requests that the Agency reconsider its denial of your [Request for Correction \(RFC\) 21005](#), in which you requested that EPA re-evaluate certain conclusions on the cancer effects of chloroprene on humans set forth in the “IRIS Toxicological Review of Chloroprene (Final Report)” based on new modeling and epidemiological analysis that you submitted. Your RFR highlights issues which you assert were not addressed in our response to your RFC (see Appendix A).

In accordance with EPA’s [Information Quality Guidelines](#), a three-member executive panel met on October 3, 2022 to review your request and the information you provided. The panel determined that the original reasoning behind EPA’s denial of RFC 21005 remains sound. We emphasize that many of the points raised in the RFR were not raised in RFC 21005. Rather, RFR 21005A represents a significant expansion in the scope of issues raised (see Appendix A). EPA’s response to the RFR is limited to a reconsideration of issues raised in RFC 21005 and a determination if corrective action is appropriate ([EPA’s Information Quality Guidelines](#)).

As noted in [EPA’s denial of RFC 21005](#), the RFC process is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality standards. The 2010 IRIS Chloroprene Toxicological Review was subject to rigorous independent peer review and public comment in 2009. Consistent with EPA’s Information Quality Guidelines, this peer review is presumptive of objectivity and “best available” science at the time it was developed. The Information Quality Guidelines commits EPA to ensure, “to the extent practicable,” that: “The substance of the information is accurate, reliable, and unbiased. This involves the use of (i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer-reviewed science and supporting studies”.... “In applying these principles, “best available” usually refers to the availability at the time an assessment is made.”

After careful reconsideration of issues raised in RFR 21005A, the Executive Panel has determined that the underlying information and conclusions presented in the 2010 IRIS Toxicological Review of Chloroprene

and its supporting materials are consistent with EPA's Information Quality Guidelines. Hence the RFR is denied.

For additional context, EPA's Information Quality Guidelines recognize that scientific knowledge about chemical hazards and risk changes and may need to be updated over time. However, the RFC process is not a mechanism to commit EPA to undertake scientific updates of its risk assessment products, such as IRIS Toxicological Reviews. EPA's Information Quality Guidelines recognize that a decision to launch an updated assessment depends on important programmatic factors and resource availability. Given the finite resources of the IRIS Program, IRIS assessment activities are based on the priority needs of EPA National Program and Regional Offices identified through a structured internal nomination process. Any new scientific information submitted through the RFC process would be considered if an update was initiated based on (1) the topic being identified as a National Program or Regional Office priority need, and (2) acceptance of the nomination by the IRIS Program given available resources. Importantly, the availability of new scientific information does not necessarily mean that existing IRIS toxicity values are outdated or not based upon the best available science.

EPA remains committed to the guidelines established by the Office of Management and Budget for maximizing the quality, integrity, objectivity, and reproducibility of information we disseminate to the public.

Thank you for your interest in EPA's information quality.

Sincerely,

VAUGHN NOGA

Digitally signed by VAUGHN NOGA
Date: 2022.10.19 08:23:35 -04'00'

Vaughn Noga, Chief Information Officer and
Deputy Assistant Administrator for Environmental Information

Appendix A: RFC 21005 Scope Analysis

EPA's response to the RFR is limited to a reconsideration of issues raised in RFC 21005. This appendix identifies the comments which aligned with the RFC and those that are new in the RFR, using the language (headers and sections) found in the RFR.

RFR Issues Within the Scope of the July 2021 RFC Submitted by DPE:

A. ORD's denial of the RFC on grounds that DPE had not identified errors in the 2010 review is incorrect And Constituted An Arbitrary And Capricious Re-Interpretation Of The Information Quality Guidelines [pp. 7-11]

2. *ORD arbitrarily and capriciously "moved the goal posts" in rejecting the consideration of new scientific evidence [pp. 7-11]*

B. ORD Is Mistaken – The 2010 Peer Review And ORD's Response To The 2010 Peer Review Support The Granting Of The RFC. [pp. 12-18] "ORD's 'Courtesy Technical Review' incorrectly interpreted the PBPK model and health data as consistent with the IUR"

3. *The 2010 Peer Review Report identifies the need for the PBPK Model [p. 16]*

C. ORD Failed to Evaluate Required Factors Under the Information Quality Guidelines [pp. 18-23]

1. *The Information Quality Guidelines and the Case Law Specify the Factors to be Evaluated with Scientific Updates [pp. 18-21]*

5. *In denying the RFC, ORD ignored DPE's proposal for a compartmentalized update of only the IUR within the 2010 Review [p. 23]*

D. ORD's "Courtesy Technical Review" Incorrectly Interpreted the PBPK Model and Health Data as Consistent with the IUR [pp. 23-27]

1. *The 2021 PBPK Model is Peer Reviewed and Ready for Use, and shows that the 2010 IUR should be corrected, at the very least, by a factor of 35 [pp. 24-26]*

2. *The Courtesy Technical Review Incorrectly Concludes that an IUR Revision Based on the PBPK Model Would only Increase the IUR by a Factor of 2 [pp. 26-27]*

E. New Health Data Confirm That The IUR Should be Revised [pp. 27-30]

2. *The Ramboll RFR Report identifies what the Courtesy Technical Review Got Wrong [pp. 29-30].*

RFR Issues Outside of the Scope of the July 2021 RFC Submitted by DPE:

A. ORD’s denial of the RFC on grounds that DPE had not identified errors in the 2010 review is incorrect And Constituted An Arbitrary And Capricious Re-Interpretation Of The Information Quality Guidelines [pp. 7-11]

1. *RFC #21005 Identified Errors in the 2010 Review [p. 7]*

B. ORD Is Mistaken – The 2010 Peer Review And ORD’s Response To The 2010 Peer Review Support The Granting Of The RFC. [pp. 12-18] “ORD’s ‘Courtesy Technical Review’ incorrectly interpreted the PBPK model and health data as consistent with the IUR”

1. *The 2010 Peer Review shows that ORD “grossly misrepresented” the epidemiological data [pp. 12-14]*

2. *ORD failed to adjust for the overestimate of risk from the female B6C3F1 mouse Highlighted by the 2010 Peer Review [pp. 14-16]*

4. *EPA’s 2010 Response to the External Peer Review and Public Comments showed a gross disparity between estimated and observed lung and liver cancers [pp. 17-18]*

C. ORD Failed to Evaluate Required Factors Under the Information Quality Guidelines [pp. 18-23]

2. *ORD should have considered how the failure to update the chloroprene IUR affects the Clean Air Act Requirements [pp. 21-22]*

3. *Revising the IUR will have a substantial impact on the updated information on public policies, including but not limited to Environmental Justice [p. 22]*

4. *Revising the IUR will have a substantial impact on private sector decisions, such as DPE’s investments in the Louisiana Neoprene plant [p. 22]*

E. New Health Data Confirm That The IUR Should be Revised [pp. 27-30]

1. *The Marsh Epidemiology Studies and EPA’s Misinterpretation of the Marsh Studies in 2010, show that the RFC Should be Granted [pp. 27-29]*